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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,358	10/28/2003	Joseph Page	262.3	5944

7590

02/16/2006

Joseph Page  
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La Jolla, CA 92038

EXAMINER
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BERHANU, ETSUB D

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/695,358	Applicant(s) PAGE ET AL.	
	Examiner Etsub D. Berhanu	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/28/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Element 64, Figure 6. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the symmetry axis of the coupling disk must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing

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date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

3. Claim 1 is objected to because of the following informalities: line 5 of the claim does not agree with line 4 of the claim. It is suggested that line 5 of the claim be changed to include "into and from human flesh" to properly parallel "to and from at least one acoustic transducer" stated in line 4 of the claim. Appropriate correction is required.
4. Claims 4 and 16 are objected to because of the following informalities: they both appear to be dependent on the incorrect claim. Claim 4 should be dependent on claim 2, otherwise "said measurement head" lacks antecedent basis. Claim 16 should be dependent on claim 15, otherwise "said dense material" lacks antecedent basis. Appropriate correction is required.
5. Claims 6-8 and 11 are objected to because they recite phrases inconsistent with a previously claimed part of the invention. The term "said optical coupling means" should be used throughout the claims to maintain consistency.
6. Regarding claim 17, "an aperture" should be recited to make the claim clear.

### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "said coupling" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is unclear which coupling the applicant further intends to limit.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationship is: the relationship between an optical source and the disposable couplings.

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 8, 10 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, specifically, the claims include human tissue as part of the claimed subject matter. It is suggested that the claims be amended to include the phrase "adapted/configured to" to eliminate human tissue as part of the invention.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-4, 6, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Rule et al.'872 (US Publication No. 2003/0032872).

Regarding claims 1-4, 6, and 11, Figure 4 of Rule et al.'872 discloses a thin, disk shaped element 100 having axial symmetry; optical and acoustic coupling means 104 (the left half of aperture 104, herein referred to as 104L, is capable of being used as an optical coupling means while the right half of aperture 104, herein referred to as 104R, is capable of being used as an acoustic coupling means); spatial coupling means 106 and 106' to promote spatial stability and reduce movement between said coupling and a tissue test site; and spatial coupling means 108, 108', 110 and 110' to temporarily affix said disk to a measurement head. The optical coupling means 104L is arranged on a symmetry axis of the disk and is an aperture cut into the substrate.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 7, 9, 12, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rule et al.'872 further in view of Rohrscheib et al.'774 (US Patent No. 6,718,189).

Rule et al.'872 teaches all the elements of the current invention, as discussed in paragraph 12, except for optical coupling means including an index matching fluid and a lens operable for focusing and concentrating light into abbreviated tissue space; and acoustic coupling means comprised of a plurality of apertures in the substrate which includes multiple regions distributed about an annulus, at least one acoustic conduit and a mesh element within an aperture cut into the substrate, wherein the acoustic conduit includes holes through the substrate, is a dense material press fit into receiving holes in the substrate, and wherein said dense material includes a curved contact surface suitable for being directly in contact with skin surface.

In the same field of endeavor, Rohrscheib et al.'774 teaches that: index-matching fluid is used to optimize introduction of light into the tissue, reduce specular light and effectively get light out of the tissue (col. 9, lines 50-54); that a dense, deformable solid, capable of changing shape, may be used as an index-matching fluid (col. 13, lines 1-8); an optical lens focuses light energy to a high energy density spot and that other beam focusing means may be used to alter the area of illumination of an energy source (col. 20, lines 21-29).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical coupling means of Rule et al.'872 to include index matching fluid and a lens, as taught by Rohrscheib et al.'774, since index matching fluid improves the efficiency of coupling light both into and out of a tissue sample and a lens is capable of focusing light energy onto a desired tissue space.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the acoustic coupling means of Rule et al.'872 to be made of a dense deformable index matching solid, as taught by Rohrscheib et al.'774, since the deformable index matching solid improves the efficiency of coupling light energy out of a tissue sample, thus providing communication between tissue and a detector. Further, because the deformable solid is able to change shape, it is capable of being press

fit into receiving holes of the substrate and it is capable of including a curved contact surface suitable for being directly in contact with skin surface.

16. Claims 13, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rule et al.'872 in view of Rorscheib et al.'774 as applied to claims 7, 9, 12, 15 and 16 above, and further in view of Percy'620 (US Patent No. 3,859,620).

Rule et al.'872 in view of Rorscheib et al.'774 teaches all the elements of the current invention, as discussed in paragraph 15, except for an acoustic conduit including holes or vias through said substrate, the acoustic coupling means including a mesh element within an aperture cut into said substrate, said substrate including multiple regions about an annulus, and the acoustic coupling means including a plurality of apertures in the substrate.

Percy'620 teaches that a mesh-shaped design makes the framework transparent to acoustic energy, thus avoiding the problems associated with reflections in an acoustic array (col. 3, lines 33-36), and that the mesh design allows acoustic energy to pass through the framework (col. 3, lines 39-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the acoustic conduit of Rule et al.'872 in view of Rorscheib et al.'774 to include a mesh shaped design (thus containing holes), as taught by Percy'620, since a mesh shaped design allows acoustic energy to pass through the framework.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the acoustic coupling means of Rule et al.'872 in view of Rorscheib et al.'774 to include a mesh element, as taught by Percy'620, since a mesh framework avoids problems associated with reflections in an acoustic array.

It is noted that Figure 4 of Rule et al.'872 containing the index matching fluid, deformable index matching solid and lens, as modified by Rorscheib et al.'774, and the mesh designed acoustic conduit as



modified by Percy'620, thereby is a substrate including multiple regions distributed about an annulus, wherein the acoustic coupling means includes a plurality of apertures in the substrate.

17. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rule et al.'872 in view of Rohrscheib et al.'774 and further in view of Percy'620 as applied to claims 13, 17, 19 and 20 above, and further in view of Qin et al.'072 (US Publication No. 2005/0283072).

Rule et al.'872 in view of Rohrscheib et al.'774 and further in view of Percy'620 teaches all the elements of the current invention, as discussed in paragraph 16, except for a mesh element including an attached acoustic coupling gel.

Qin et al.'072 teaches that acoustic coupling gel provides a low loss path for acoustic energy (page 5, section [0055], lines 1-6).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the mesh element of Rule et al.'872 in view of Rohrscheib et al.'774 and further in view of Percy'620 to include an acoustic coupling gel thereon, as taught by Qin et al.'072, since acoustic coupling gel provides a low loss path for acoustic energy.

18. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rule'021 in view of Chou'728 (US Patent No. 6,049,728).

Rule'021 teaches all the elements of the current invention, as discussed in paragraph 12, except for a durable wearable portion comprising an optical source and an acoustic transducer.

Chou'728 discloses a durable apparatus for noninvasive measurement of blood glucose by photoacoustics comprising an optical source (Figure 1, source 12) and an acoustic transducer (Figure 2, microphone 32).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the coupling element of Rule'021 with the durable wearable portion comprising an optical source and an acoustic transducer, as taught by Chou'728, since the apparatus of Chou'728 is capable of

measuring blood glucose and the coupling element of Rule'021 is capable of attaching said apparatus to a tissue test site.

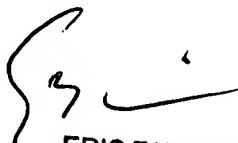
***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571.272.4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDB

  
ERIC F. WINAKUR  
PRIMARY EXAMINER